

Message

From: Sarah Berger [sarah.berger@bayer.com]
Sent: 11/9/2021 7:20:38 PM
To: Schmid, Emily [Schmid.Emily@epa.gov]
CC: BCSReg_Archive [esepamailbox@bayer.com]
Subject: RE: 524-544 Glyphosate registration PPLS issue

Hi Emily,

Thank you for the guidance. We'll get the notification submitted soon.

Thanks,
Sarah

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Tuesday, November 09, 2021 1:19 PM
To: Sarah Berger <sarah.berger@bayer.com>
Cc: BCSReg_Archive <esepamailbox@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: 524-544 Glyphosate registration PPLS issue

Hi Sarah,

Sorry I didn't get back to you sooner. I wanted to check in with the reviewer who is working on the label amendment for this product to see how long he'll need to complete it. I think it's going to be a lengthy review so your best option is to update the label by notification.

You'll need to go back to the last stamped accepted label (not supplementals) from June 25, 2009 and the only differences between that label and the one you submit as a notification can be the changes noted in the letter and anything that can be updated via notification. Storage and Disposal can be updated by notification per PRN 2007-4. Send us (via the portal) a highlighted label indicating all of the changes you are making from the June 25, 2009 label along with the cover letter and application form required for a label notification.

Let me know if you have any questions.

Best regards,
Emily

From: Sarah Berger <sarah.berger@bayer.com>
Sent: Tuesday, November 09, 2021 10:48 AM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: BCSReg_Archive <esepamailbox@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: 524-544 Glyphosate registration PPLS issue

Emily,

Following up on the glyphosate label question below for 524-544. This is a bit time sensitive due to the Dec 23 deadline for use of Monsanto labels.

Please let me know if you have any questions. I can be reached at 636-628-1289.

Thank you,

Sarah

From: Sarah Berger
Sent: Monday, November 01, 2021 10:40 AM
To: schmid.emily@epa.gov
Cc: BCSReg_Archive <esepamailbox@bayer.com>
Subject: 524-544 Glyphosate registration PPLS issue

Emily,

I am reaching out due to an issue we are having with Bayer's 524-544 glyphosate (RT3) registration in Texas- I believe the easiest path forward is to update PPLS with a correct label, but I am seeking your input.

Texas recently rejected our label submission for 524-544 which was a change from Monsanto company name and address to Bayer company name and address. The Texas reviewer indicated that in PPLS, the most recently *stamped* label (July 15, 2010) does not have complete storage and disposal information or language updates called out in approved label amendment dated June 25, 2009. For some reason, label booklets were submitted by Monsanto and stamped and then posted to PPLS in July 2009 and July 2010, which is the most recently stamped label that Texas must refer to.

Texas is requesting to have a stamped Master Label, which includes complete storage and disposal language as well as the 2009 required language changes, posted into PPLS. What is the best path to achieve this? Texas would also accept a notification submitted to EPA (we would provide contents of notification and CDX receipt to Texas), but I am unsure what the "changes" we would be notifying EPA of, since I'm assuming this label is stamped and just not posted to PPLS. From your perspective, is a notification acceptable? The notification contents would be an explanation of this issue and discrepancies in PPLS.

Thank you for your consideration of this issue. If you would like to have a call to discuss, please let me know. I can be reached at the mobile number below.

Best regards,
Sarah

Sarah Berger, Ph.D.
Senior Regulatory Affairs Manager
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